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Washington, D.C. 20231

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By

Lisa Dahline

We are transmitting herewith the attached Patent Application including the following:

- [X] 18 sheet(s) of specification.
- [X] 48 claim(s).
- [X] 1 sheet(s) of Abstract.
- [X] 6 sheet(s) of informal drawings.
- [X] Unexecuted Declaration and Power of Attorney.
- [ ] A verified statement(s) to establish small entity status under 37 C.F.R. 1.9 and/or 1.27 is enclosed.
- [ ] An Assignment of the invention to \_\_\_\_\_ is being filed contemporaneous with this patent application.
- [ ] A certified copy of a \_\_\_\_\_ application, serial no. \_\_\_\_\_, filed \_\_\_\_\_, 19\_\_\_\_\_, the right of priority of which is claimed under 35 U.S.C. 119.

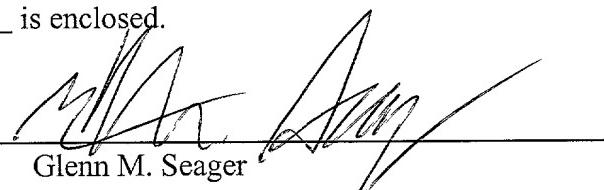
## CLAIMS AS FILED

	(1)	(2)	SMALL ENTITY		OTHER	
FOR:	# FILED	# EXTRA	Rate	Fee	Rate	Fee
BASIC FEE				\$395		\$790
TOTAL CLAIMS	48 -20 =	28	x11=	\$	x22=	\$616
INDEPENDENT CLAIMS	3-3 =	0	x41=	\$	x82=	\$0
( ) MULTIPLE DEPENDENT CLAIM PRESENTED			+135=	\$	+270=	\$0
TOTAL			\$			\$1406.00

\*If the difference in Column (1) is less than zero, enter "0" in Column 2.

[ ] Other \_\_\_\_\_.

[ ] A check in the amount of \$\_\_\_\_\_ is enclosed.

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## CATHETER HAVING IMPROVED BONDING REGION

### Field of the Invention

The present invention relates generally to medical devices. More specifically, the present invention relates to angioplasty catheters. In particular, the present invention 5 includes angioplasty catheters having distal, short, lubricious inner guide wire tubes bonded within flexible outer tubes.

### Background of the Invention

Angioplasty procedures have gained wide acceptance in recent years as efficient and effective methods for treating types of vascular disease. In particular, angioplasty is 10 widely used for opening stenoses in the coronary arteries and is used for treating stenoses in other vascular regions.

One widely used form of angioplasty makes use of a dilatation catheter which has a inflatable balloon at the distal end and a guide wire lumen within at least a portion of the catheter shaft. Typically, a guide wire is inserted through the vascular system to a 15 position near the stenoses, leaving a proximal portion of the guide wire extending from the patient. The proximal guide wire portion is threaded through the dilatation catheter guide wire lumen, and the dilatation catheter is advanced through the vascular system over the guide wire to a position near the stenoses. The treating physician manipulates the dilatation catheter until the balloon is positioned across the stenoses. The balloon is 20 then inflated by supplying fluid under pressure through an inflation lumen in the catheter to the balloon. The inflation of the balloon widens the vessel lumen through the stenosed area by pressing the inflating balloon wall against the lesion inside wall.

One class of dilatation catheters, termed "Single Operator Exchange" (SOE) or "Rapid Exchange" catheters, have only a short, distal guide wire lumen, to allow for easy removal and replacement of catheters while requiring only a short length of guide wire extending proximally from a patient. These catheters include a distal portion having  
5 multiple desired attributes. The catheter distal portion preferably has a small profile or cross-sectional area and is very flexible, to allow for traversing narrow and tortuous vessel paths. The distal portion may also require a guide wire tube having a lumen, which increases the profile. The guide wire lumen preferably has a lubricious inside wall to ease movement of the catheter over the guide wire.

10 Many current SOE catheters have outer polyethylene tubes and inner polyethylene guide wire tubes inserted therein. An orifice can be created in the side of the outer tube wall and the inner tube inserted through the orifice. The inner tube is inserted so as to extend longitudinally through the lumen of the outer tube. On one side of the inner tube, distal of the orifice, the outside surface of the inner tube runs close to the inside surface of the outer tube. On the opposite direction, proximal of the orifice, the outside surface of the inner tube runs along the outside surface of the outer tube, in a crimped or buckled hollow surface region. The close proximity of the tube surfaces suggests bonding using adhesive or heat bonding. Heat bonding is preferred to adhesive bonding.  
15

Polyether block amide (PEBA) tubes have greater flexibility than polyethylene tubes, and it would be desirable to use PEBA tubes for the outer tubes. It is very desirable to have the inner and outer tubes formed of mutually compatible materials to enable heat bonding. Use of PEBA for guide wire inner tubes would provide such heat bonding compatibility. PEBA is generally less lubricious than polyethylene, however,  
20

making polyethylene a more desirable material for forming the inner tube. Lubricity is important for providing a low friction inner surface for accepting a guide wire. What would be desirable is a catheter allowing for use of a more flexible outer tube while retaining the benefits of a more lubricious inner tube while allowing high-quality heat  
5 bonding between the two tubes.

#### Summary of the Invention

The present invention includes catheters having a first tube formed primarily of a first material bonded to a second tube having an inside surface formed primarily of a second material, where the first and second materials may be unsuited for high quality  
10 direct bonding. One catheter has a first tube formed of a flexible material such as polyether block amide and a second, tri-layer tube having a lubricious inside layer such as polyethylene, a flexible outside layer formed of the same material as the first tube outside surface, and an intermediate tie-layer suitable for joining the lubricious and flexible layers. In a preferred embodiment, the first tube has an orifice through a wall  
15 and the second tube is inserted through the wall and distally disposed within the first, outer tube. In a preferred embodiment, the first tube functions as a distal catheter shaft and the second tube functions as a short, distal guide wire tube disposed within, and bonded to, the first tube.

Catheters incorporating the invention include single operator exchange (SOE)  
20 angioplasty balloon catheters having a proximal shaft, a distal shaft including a first tube coupled to the proximal shaft, distally disposed inflatable balloon, and an orifice through the wall of the first tube disposed proximal of the balloon. In these catheters, a second guide wire tube can be inserted through the orifice and disposed distally of the orifice,

commonly extending through the balloon region and ending in a distal guide wire port near the distal end of the catheter. The SOE catheters preferably have a lubricious material forming the inside layer of the inner tube and a flexible material forming most of the outer tube. A preferred lubricious material is polyethylene (PE) and a preferred flexible material is polyether block amide (PEBA).

One SOE catheter has a polyethylene inner tube disposed within a tri-layer outer tube having an inside PE layer, an outer PEBA layer, and a PLEXAR™ tie-layer disposed therebetween. The outer tube inside surface can be bonded to the inner tube outside surface. Another SOE catheter has a PE inner tube disposed within an interrupted tri-layer outer tube having a proximal PE portion, a distal PEBA portion, and a tie-layer interrupting the PE and PEBA portions. The inner tube outside surface can be bonded to the outer tube PE portion inside and outside surfaces. Another SOE catheter has a PEBA outer tube and an interrupted tri-layer inner tube disposed therein having a proximal PEBA portion, a distal PE portion, and a tie-layer disposed therebetween. The inner tube PEBA portion can be bonded to the outer tube PEBA inside and outside surfaces. Another SOE catheter includes a PEBA outer tube and a PE inner tube having a proximal tri-layer portion having a tie-layer disposed over the inside PE layer and a PEBA layer disposed over the tie-layer. The inner tube proximal portion outside PEBA surface can be bonded to the outer tube PEBA inside and outside surfaces.

Yet another SOE catheter includes a PEBA outer tube and a tri-layer inner tube having a PE inside layer, a PEBA outside layer, and a tie-layer disposed therebetween. The inner tube outside PEBA surface can be bonded to the outer tube PEBA inside and outside surfaces. In still another SOE catheter, an outer PEBA tube has a bi-layer inner

tube disposed within including an inside high density PE (HDPE) layer and a PLEXAR™ tie-layer disposed over the HDPE inside layer. The inner tube outside tie-layer can be bonded to the outer tube PEBA inside surface. In one more embodiment, an SOE catheter includes a PEBA outer tube and an inner tube having a proximal PEBA portion butt-welded to a distal tri-layer portion having a PE inside layer, a PEBA outside layer, and a tie-layer disposed therebetween.

The present invention can provide catheters having the advantages of a lubricious guide wire tube, a flexible catheter shaft, and a secure bond between the lubricious material and the flexible material. Catheters according to the present invention can provide the advantages of both materials as well as providing the advantages of heat bonding the two materials.

#### Brief Description of the Drawings

Figure 1 is a longitudinal, cross-sectional view of a balloon angioplasty catheter including an inner guide wire tube inserted through an orifice in an outer tube and disposed within the outer tube;

Figure 2 is a fragmentary, longitudinal cross-sectional view of a distal portion of the catheter of Figure 1, illustrating an inner tube extending through an orifice in an outer tube;

Figure 3 is a transverse, cross-sectional view taken through 3-3 in Figure 1, illustrating an outer tube, an inner tube, and a core wire;

Figure 4 is a longitudinal, cross-sectional view of an inner guide wire tube inserted within and bonded to a tri-layer outer tube, wherein the outer tube has an inside surface compatible with the outside surface of the inner tube;

Figure 5 is a longitudinal, cross-sectional view of a tri-layer inner guide wire tube inserted within and bonded to an outer tube, wherein the inner tube has an outside surface compatible with the inside surface of the outer tube;

Figure 6 is a longitudinal, cross-sectional view of an inner guide wire tube  
5 inserted within and bonded to an interrupted tri-layer outer tube, wherein the outer tube has a proximal portion inside surface compatible with the outside surface of the inner tube, an intermediate portion tie-layer, and a distal portion having different properties than the proximal portion;

Figure 7 is a longitudinal, cross-sectional view of an interrupted tri-layer inner  
10 guide wire tube inserted within and bonded to an outer tube, wherein the inner tube has a proximal portion outside surface compatible with the inside surface of the outer tube, an intermediate portion tie-layer, and a distal portion having different properties than the proximal portion;

Figure 8 is a longitudinal, cross-sectional view of an inner guide wire tube  
15 inserted within and bonded to an outer tube, wherein the inner tube has a short, proximal tri-layer portion having an outside surface compatible with the inside surface of the outer tube and a distal portion having an outside surface corresponding to the inside layer of the tri-layer portion;

Figure 9 a longitudinal, cross-sectional view of a bi-layer inner guide wire tube  
20 inserted within and bonded to an outer tube, wherein the inner tube has an outside tie-layer compatible with the inside surface of the outer tube; and

Figure 10 is a longitudinal, cross-sectional view of an inner guide wire tube inserted within and bonded to an outer tube, wherein the inner tube has a proximal

portion having an outside surface compatible with the inside surface of the outer tube and a distal portion having different properties than the proximal portion butt-welded to the proximal portion.

Detailed Description of the Preferred Embodiments

5       Figure 1 illustrates a balloon angioplasty catheter 20, which demonstrates one catheter incorporating the present invention. Catheter 20 extends from a proximal region 22 through an intermediate region 24 to a distal region 26. Proximal region 22 includes a manifold 28, a strain relief 30, and a proximal shaft 32. Proximal shaft 32 includes a proximal region 34 having an outer hypotube construction and a distal region 36 having a 10 polymeric construction, continuing distally after the hypotube terminates. The term “hypotube,” as used herein, refers generally to a thin walled, high-strength metallic tube having a lumen within. The hypotube is preferably a stainless steel hypodermic tube. In one embodiment, a core wire or stiffener 37 can be included in proximal region 22 and intermediate region 24 to provide additional stiffness and pushability to catheter 20 to 15 enable pushing the catheter distal portion into distant body regions without buckling.

A distal shaft 42 includes an outer tube 46 and an orifice 48 through the outer wall of outer tube 46 and a lumen 47 within. A balloon 50 is disposed distally on distal shaft 42, having an envelope 52, a proximal waist 54, and a distal waist 56. An inner tube 58 is inserted into outer tube 46 and lumen 47 through orifice 48. Inner tube 58 serves as a 20 distal guide wire tube in catheter 20. The relatively short length of inner tube 58 allows the single operator or rapid exchange of catheter 20 over a guide wire. Inner tube 58 includes a proximal orifice 70, a proximal end 71, a proximal portion 60, an intermediate portion 62, a distal portion 64, a distal end 66, a distal orifice 68, and a guide wire lumen

59 within. In use, a guide wire (not requiring illustration) can be threaded through proximal orifice 70, through lumen 59, exiting through distal orifice 68. Inner tube 58 is preferably substantially congruent within outer tube 46 for much of the length of inner tube 58. The entry of inner tube 58 through orifice 48 can include a buckled or concave 5 region 72, also illustrated in Figure 2 at 806. In this buckled region, inner tube 58 can lie atop outer tube 46 proximal of entry orifice 48. The entry of inner tube 58 into outer tube 46 preferably includes bonding or affixing of the tubes to secure inner tube 58 in place. This bonding preferably includes bonding in the region proximate orifice 48 and can include bonding both proximal and distal of orifice 48.

10 Referring now to Figure 2, the region proximate the entry of the inner tube into the outer tube is illustrated in greater detail. The embodiments illustrated in Figures 4-10 can share many of the structural features of the embodiment of Figure 2, while having different tube construction and bonding. Figure 2 illustrates a catheter distal region 800 including an outer tube 802 having an orifice 804 therein and an inner guide wire tube 15 805 inserted distally through orifice 804. An orifice such as orifice 804 can be formed by making a slit or removing material and creating a hole in the outer tube wall. The orifice can serve to admit the inner tube into the outer tube. Inner tube 805 includes a proximal end 810, a proximal portion 812, a proximal orifice 808, and a guide wire lumen 816 through inner tube 805. Inner tube 805 lies in a buckled or concave region 806 in outer 20 tube 802 proximal of where inner tube proximal portion 812 extends into outer tube 802. In one embodiment, the bonding region lies generally proximate orifice 804, which can be used for bonding of inner tube 805 to outer tube 802. Inner tube 805 includes an inner tube wall 818, an inside wall surface 822, and an outside wall surface 820. Inner tube

805 includes a distal portion 814, which lies distal of proximal portion 812. Outer tube 802 includes a proximal portion 830, a tube wall 831, an outside wall surface 832, and an inside surface 840.

In one embodiment, inner tube wall 818 is formed of a lubricious material to provide a lubricious inside surface 822 offering less resistance when advancing the catheter over a guide wire. In this embodiment, outer tube wall 831 is formed of the same or compatible lubricious material as inner tube 805. This allows bonding between inner and outer tubes as indicated, for example, at region 850. In some embodiments, bonding occurs distal of orifice 804 and near orifice 804. In other embodiments, the bonding occurs further distal of orifice 804. In other embodiments, bonding occurs proximal of orifice 804 as indicated, for example, by region 851. Any suitable location for bonding inner to outer tubes is within the scope of the invention.

Referring now to Figure 3, a transverse cross section taken through 3-3 in Figure 1 is further illustrated. Outer tube 46 has been heat bonded to inner tube 58, resulting in an area of melted polymer 47 between the inner and outer tubes. Guide wire lumen 59 is illustrated, together with core wire 37 and an inflation lumen 61. In one method, after the inner tube is positioned within the outer tube, mandrels corresponding to the guide wire and inflation lumens are positioned within the inner and outer tubes respectively. The tubular assembly is heated, resulting in a re-melt or re-flow of polymeric material and heat bonding.

Referring now to Figure 4, a catheter distal region 100 is illustrated, including an outer tube 102 having an orifice 104 therein, and an inner guide wire tube 105 inserted distally through orifice 104. Inner tube 105 includes a proximal portion 112 and a guide

wire lumen 116 through inner tube 105. Inner tube 105 lies in a buckled or concave region 106 in outer tube 102 proximal of where inner tube proximal portion 112 extends into outer tube 102. In one embodiment, the bonding region lies generally proximate orifice 104, which can be used for bonding of inner tube 105 to outer tube 102. Inner 5 tube 105 includes an inner tube wall 118, an inside wall surface 120, and an outside wall surface 122. Inner tube 105 includes a distal portion 114, which lies distal of proximal portion 112. Outer tube 102 includes a proximal portion 130, a tube wall 131, an outside wall surface 132, an outside layer 134, an intermediate tie-layer 136, an inside layer 138, and an inside surface 140.

10       In one embodiment, inner tube wall 118 is formed of a lubricious material to provide a lubricious inside surface 120 offering less resistance when advancing the catheter over a guide wire. In this embodiment, outer tube wall inside surface 140 is formed of the same or compatible lubricious material as inner tube 105. This allows bonding between inner and outer tubes as indicated in region 150. As illustrated in 15 Figure 4, inner tube 105 and outer tube inner layer 138 are formed of the same material. After heat bonding, the two layers can melt and flow together as indicated by the dashed line between layer 138 and inner tube wall 105. In the example illustrated, bonding only occurs distal of orifice 104 and near orifice 104. In other embodiments, the bonding occurs further distal of orifice 104. Any suitable location for bonding inner to outer tubes 20 is within the scope of the invention. Outer tube 102 has an outside layer 134 formed of a flexible material different from the lubricious material forming inner tube 105. Disposed between outside layer 134 and inside layer 138 is tie-layer 136.

Tie-layer 136, as used herein, refers to a layer which enables or enhances the bonding of the two materials such as the outside and inside layers to one another. The outer tube outside and inside layers can provide different properties desirable for the catheter. In particular, the outside layer can contribute much of the structural properties  
5 of the outer tube, while the inside layer can contribute an inside surface that is bond compatible with the outside surface of the inner tube. The tie-layer is preferably a layer of polymer that is bond compatible with both inside and outside layers. The tie-layer can in turn be formed of more than one layer, but a single layer is preferred to provide a thin tube wall. In some embodiments, the tie-layer enables two materials to bond to one  
10 another where such bonding would not occur in the absence of the tie-layer. In other embodiments, the tie-layer enhances bonding, improving the bond strength over that which would otherwise occur. A tie-layer can greatly improve the quality of bonding.

In one embodiment, inner tube 105 is formed of polyethylene, outer tube inside layer 138 is also formed of polyethylene, and outer tube outside layer 134 is formed of a  
15 polyether block amide (PEBA) such as PEBA<sup>TM</sup>. A tie-layer suited for bonding polyethylene and PEBA together such as PLEXAR<sup>TM</sup> or KRATON<sup>TM</sup> is used for tie-layer 136 in one embodiment. In some embodiments, a surface treatment can be used to form the tie-layer. In an embodiment having a polyethylene inner tube, the polyethylene provides a lubricious inside tube surface for a guide wire to slide within. In an  
20 embodiment having a PEBA outer tube outer layer, the PEBA provides a strong, yet flexible material, having superior flexibility to polyethylene in most catheter applications. The flexibility is of importance in the distal catheter region, which may be required to traverse tortuous secondary and tertiary coronary vessels.

The polyethylene inner tube provides the advantages of a lubricious inner surface, while the tri-layer outer tube provides flexibility imparted by the PEBA outside layer. The polyethylene outer tube inside layer provides a layer compatible for heat bonding with the polyethylene inner tube outside surface. The outer tube tie-layer provides a  
5 means for joining the outer tube polyethylene and PEBA layers. Catheter distal region  
100 thus has the advantages of a lubricious guide wire lumen and the advantages of a  
distal catheter outer tube formed of a flexible material.

Referring now to Figure 5, another embodiment of the invention is illustrated in a catheter distal region 200 including an inner tube 205 disposed within an orifice 204 in an  
10 outer tube 202. Outer tube 202 includes a proximal portion 230, a tube wall 231, an outside surface 232, and an inside surface 240. Outer tube 202 and tube wall 231 are formed of a first material extending from outside surface 232 to inside surface 240. Inner tube 205 includes a tube wall 218 having an inside surface 220, an inside layer 221, a tie-layer 225, an outside layer 223, and an outside surface 222. Inner tube inside layer 221 is  
15 formed of a second, lubricious material, and outside layer 223 is preferably formed of the first material or a material bond compatible with the first material. Tie-layer 225 provides a bond, holding inside layer 221 and outside layer 223 together. Outer tube inside surface 240 and inner tube outside surface 222 are formed of the same first material, allowing for formation of a good heat bond securing the inner tube within the  
20 outer tube. In the bonding region proximate orifice 204, the inner and outer tubes are secured at a distal bonding region 250 disposed distal of orifice 204 and at a proximal bonding region disposed proximal of orifice 204, better visualized by bonding region 851 in Figure 2, as are other bonding regions disposed proximal of the orifice in figures

similar to Figure 5. Outer tube 202 can be bonded to inner tube 205 using both outer tube inside surface 240 and outside surface 222. In a preferred embodiment, the first material forming outer tube 202 is PEBA, as is the material forming inner tube outside layer 223, while the second material forming inner tube inside layer 221 is polyethylene. The 5 embodiment illustrated thus can have a lubricious polyethylene inside surface for the guide wire lumen and a flexible PEBA outer tube.

Referring now to Figure 6, a catheter distal region 300 having an interrupted tri-layer outer tube is illustrated. Catheter distal region 300 includes an inner tube 305 disposed within an orifice 304 in an outer tube 302. Inner tube 305 includes a wall 318, an inside surface 320, and an outside surface 322. Outer tube 302 includes a tube wall 331 having an inside surface 340, an outside surface 332, a proximal portion 330, a distal portion 342, and an intermediate portion 337 disposed between the proximal and distal portions. In a preferred embodiment, intermediate portion 337 includes a tie-layer 336 formed as a short layer disposed at an angle relative to the tube wall, such that tie-layer 336 extends over a length indicated at "D1" in Figure 6. Tie-layer 336, as illustrated, longitudinally separates or interrupts the proximal and distal portions of the layer. In a preferred embodiment, D1 has a length between about one (1) mm and one hundred (100) mm and a width of about one hundred (100) mm. In one method, tie-layer 336 is formed using a Short and Controlled Transition Section (SCTS) extrusion 10 technique, as described in U.S. Patent No. 5,533,985, issued to Wang, herein incorporated by reference. In one embodiment, inner tube 305 is formed of polyethylene, and outer tube 302 has proximal portion 330 formed of polyethylene, tie-layer 336 15 formed of PLEXAR™, and distal portion 342 formed of PEBA. In one embodiment,

inner tube outside surface 322 is bonded to outer tube inside surface 340, as indicated at 350 and by region 851 in Figure 2 as discussed previously. In embodiments supporting bonding involving both the inside and outside surface of the outer tube, the bonding region can extend both proximal and distal of orifice 304. Bonding can also extend over 5 the sides of inner tube 305 but is not illustrated in the longitudinal, cross-sectional view of Figure 6. The embodiment of Figure 6 thus provides a lubricious inner tube for ease of guide wire movement and an outer tube proximal portion for bonding to the lubricious inner tube, while providing a flexible material forming most of the outer tube.

Referring now to Figure 7, a catheter distal region 400 having an 10 interrupted tri-layer inner tube is illustrated. Catheter distal region 400 includes an outer tube 402 having an inner tube 405 disposed within an orifice 404 in outer tube 402. Inner tube 405 includes a proximal portion 412, a distal portion 414, and an intermediate portion 413 having a length indicated at "D2". Intermediate portion length D2 is preferably between about one (1) mm and fifty (50) mm. Intermediate portion 413 15 includes a tie-layer 436 preferably disposed at an angle relative to the inner tube wall. In one method, tie-layer 436 is formed using a Short and Controlled Transition Section (SCTS) extrusion technique previously described. Outer tube 402 and inner tube proximal portion 412 are preferably formed of the same flexible material to allow for improved bonding. Inner tube distal portion 414 is preferably formed of a lubricious 20 material, while tie-layer 436 is preferably formed of a material suitable for adhering the flexible and lubricious materials together. In one embodiment, the inner tube proximal portion 412 is bonded to outer tube 402, as indicated at 450 and by region 851 in Figure 2. The embodiment illustrated thus provides a lubricious material for most of the length

of inner tube 405, while providing a flexible material for outer tube 402. Forming inner tube proximal portion 412 of a bond compatible or identical material to the material of the outer tube allows bonding together of the inner and outer tubes.

Referring now to Figure 8, a catheter distal region 500 is illustrated having an  
5 inner tube 505 inserted into an orifice 504 in an outer tube 502. Inner tube 505 includes a  
tube wall 518, a proximal portion 512, and a distal portion 514. In proximal portion 512,  
inner tube wall 518 includes an inner layer 517, which is preferably formed of the same  
material as the entire tube wall at distal portion 514, a tie-layer 536 disposed over the  
tube wall or inner layer 517, and an outside layer 534 disposed over the tie-layer. The  
10 proximal portion of inner tube 505 thus can have two added outer layers in the proximal  
portion. In a preferred embodiment, outer tube 502 is formed of a flexible material and  
inner tube outside layer 534 is formed of the same material, thereby allowing for bond  
compatibility between inner and outer tubes. In a preferred embodiment, inner tube wall  
518 is primarily formed of a lubricious material, and tie-layer 536 is formed of a material  
15 able to bond to both the inner lubricious material and the outer flexible material. In the  
embodiment illustrated, bonding occurs as indicated at 550 and at 851 in Figure 2. In one  
embodiment, inner tube proximal portion 512 is formed using SCTS technology  
previously described. The portion of inner tube having the tie-layer and outside layer can  
be disposed anywhere on the inner tube where bonding to the outer tube is contemplated.  
20 In one embodiment, multiple short tri-layer portions are disposed over the length of the  
inner tube. In this embodiment, the added two layers are added to an inner tube where  
needed. The additional two layers over the inner tube preserves the lubricious inner walls  
of the inner tube while improving the bonding compatibility between the inner and outer

tubes. In one embodiment, inner tube inside layer 517 and distal portion 514 are formed of polyethylene, tie-layer 536 is formed of PLEXAR™, and outside layer 534 is formed of PEBA. The embodiment provides a lubricious lumen wall for guide wire movement and a flexible catheter outer tube.

5 Referring now to Figure 9, a catheter distal region 600 is illustrated having a two-layer inner tube 605 disposed within an orifice 604 and in an outer tube 602. Inner tube 605 has a tube wall 618 formed of an inside layer 638 and an outside tie-layer 636. Inner tube inside layer 638 is preferably formed of a lubricious material and outer tube 602 is preferably formed of a flexible material different from the material forming the inner tube  
10 inside layer. Bonding between inner and outer tubes is indicated at 650, but the bonding location is varied in different embodiments. In one embodiment, inside layer 638 is formed of polyethylene, tie-layer 636 is formed of PLEXART™, and outer tube 602 is formed of PEBA. The catheter distal region illustrated in Figure 9 can have a lubricious inner tube inside wall for guide wire movement and a flexible outer tube wall.

15 Referring now to Figure 10, a catheter distal region 700 having a butt-welded proximal portion is illustrated. Catheter distal region 700 includes an inner tube 705 inserted into an orifice 704 and disposed within an outer tube 702. Inner tube 705 includes a proximal portion 712 butt-welded to a distal portion 714. A weld 713 is indicated between the proximal and distal portions. In one embodiment, outer tube 702 is  
20 formed of a flexible material and inner tube proximal portion 712 is formed of the same or a bond compatible material. Inner tube distal portion 714 can include a tri-layer tube wall as illustrated, having an inside layer 738, an outside layer 734, and a tie-layer 736 disposed between inside layer 738 and outside layer 734. In a preferred embodiment,

outer tube 712 is formed from PEBA, as is inner tube proximal portion 712. In this embodiment, inner tube distal portion 714 includes inside layer 738 formed from polyethylene, where tie-layer 736 can be formed from PLEXAR™ and outside layer 734 can be formed from PEBA. The tri-layer inner tube can provide a lubricious inner 5 surface for guide wire movement, while retaining the flexibility contribution of the PEBA outer layer. In this embodiment, bonding can occur as indicated at 750 and 851 in Figure 2. The embodiment illustrated thus has a substantial PEBA contribution to flexibility, while providing a lubricious guide wire lumen, as most of the inner tube inside layer can be formed of polyethylene.

10 Figures 4-10 illustrate embodiments of the invention including an orifice through an outer tube wall and an inner tube inserted through the orifice into the outer tube and disposed distal thereof within the outer tube lumen. In another embodiment, a guide wire tube is disposed within an outer tube without being inserted through a wall. In this embodiment, the outside surface of the inner tube is bonded to the inside surface of the 15 outer tube. Figures 4-10, and the associated text, illustrate examples of tube construction and materials compatible with this embodiment. In yet another embodiment, a first flexible tube has a second tube having a lubricious inside surface bonded to the first tube outside surface. The second tube can serve as a guide wire tube. In a variation of this embodiment, multiple short, external tubes serve as guide wire tubes. Figures 5-10, and 20 the associated text, illustrate examples of tube construction and materials compatible with these external guide wire tube embodiments. In these embodiments, the second guide wire tube outside surface is bonded to the first tube outside surface.

In a preferred method of making the present invention, the first and second tubes  
are heat bonded together in the bonding region. Other bonding methods can also be used  
to take advantage of the compatible materials presented for bonding by the present  
invention. Other bonding methods believed suitable for use with the present invention  
5 include sonic welding and solvent welding.

Numerous characteristics and advantages of the invention covered by this  
document have been set forth in the foregoing description. It will be understood,  
however, that this disclosure is, in many respects, only illustrative. Changes may be  
made in details, particularly in matters of shape, size and ordering of steps without  
10 exceeding the scope of the invention. The invention's scope is, of course, defined in the  
language in which the appended claims are expressed.

2025 RELEASE UNDER E.O. 14176

What is claimed is:

1. A catheter shaft comprising:

a first tube including a lumen, an inside wall surface, and an outside wall surface, said first tube having an orifice in a proximal portion of said first tube;

a second tube inserted through, and extending distally from, said orifice, said second tube having a length, a lumen therethrough, a proximal portion, an inside wall surface and an outside wall surface; and

a bonding region bonding said second tube outside wall surface to said first tube wall surface, said second tube inside wall surface being formed of a second, lubricious material for a majority of said second tube length, said first tube wall having a layer of a first, flexible material extending for a majority of said first tube length, said first material being different from said second material.

2. A catheter shaft as recited in claim 1, wherein said bonding region is proximate said orifice.

3. A catheter shaft as recited in claim 1, wherein said bonding region includes bonding between said first tube outside surface and said second tube outside surface proximal of said orifice and said bonding region includes bonding between said first tube inside surface and said second tube outside surface distal of said orifice.

4. A catheter shaft as recited in claim 1, wherein said second tube inside and outside wall surfaces are formed of said second material.

5. A catheter shaft as recited in claim 4, wherein said second tube wall is formed of substantially said second material therethrough.

6. A catheter shaft as recited in claim 5, wherein said first tube inside surface is formed of said second material proximate said bonding region.

7. A catheter shaft as recited in claim 6, wherein said first tube has said second material disposed over most of said first tube inside surface proximate said bonding region and distal of said bonding region.

8. A catheter shaft as recited in claim 7, wherein said first tube includes said second material as an inside layer, said first material as an outside layer, and a tie-layer disposed between said inside and outside layers.

9. A catheter shaft as recited in claim 6, wherein said second tube includes polyethylene, said first tube includes an inside layer of polyethylene, an outside layer of PEBA, and a tie-layer disposed between said inside and outside layers.

10. A catheter shaft as recited in claim 6, wherein said first tube has said inside surface formed of said second material proximate said bonding region and has said inside surface formed of said first material distal of said bonding region.

11. A catheter shaft as recited in claim 10, further comprising a transition tie-layer disposed between said first and second materials.

12. A catheter shaft as recited in claim 11, wherein said second tube includes polyethylene and said first tube includes polyethylene proximate said bonding region and said first tube is formed of PEBA distal of said tie-layer.

13. A catheter shaft as recited in claim 1, wherein said first tube inside surface includes said first material.

14. A catheter shaft as recited in claim 13, wherein said first tube inside and outside surfaces are formed of said first material.

15. A catheter shaft as recited in claim 14, wherein said first tube is formed of said first material proximate said bonding region and distal of said bonding region.

16. A catheter shaft as recited in claim 15, wherein said second tube has a proximal portion proximate said bonding region having an outside surface formed of said first material.

17. A catheter shaft as recited in claim 15, wherein said second tube is formed of said first material in said proximal portion and formed of said second material distal of said proximal portion and has a transition tie-layer therebetween.

18. A catheter shaft as recited in claim 17, wherein said first material includes PEBA and said second material includes polyethylene.
19. A catheter shaft as recited in claim 15, wherein said second tube is formed of said second material, said second tube proximal portion includes a tie-layer disposed over said second material and an outer layer of said first material disposed over said tie-layer.
20. A catheter shaft as recited in claim 19, wherein said first material includes PEBA and said second material includes polyethylene.
21. A catheter shaft as recited in claim 15, wherein said second tube has said inside layer formed of said second material, a tie-layer disposed over said inside layer, and an outside layer formed of said first material disposed over said tie-layer.
22. A catheter shaft as recited in claim 21, wherein said first material includes PEBA and said second material includes polyethylene.
23. A catheter shaft as recited in claim 15, wherein said second tube proximal portion is formed of said first material and said second tube distal of said proximal portion is bonded to said proximal portion and has an inside layer formed of said second material, a tie-layer disposed over said inside layer, and an outer layer formed of said second material disposed over said tie-layer.

24. A catheter shaft as recited in claim 23, wherein said first material includes PEBA and said second material includes polyethylene

25. A catheter shaft as recited in claim 15, wherein said second tube proximal and distal portions have an inside layer formed of said second material and an outside tie-layer disposed over said inside layer.

26. A catheter shaft as recited in claim 25, wherein said first material includes PEBA and said second material includes polyethylene, wherein said second tube outside tie-layer wall surface is heat bonded to said first tube inside wall PEBA surface proximate said orifice.

27. A catheter shaft comprising:  
a first tube including a lumen, an inside wall surface, and an outside wall surface;  
a second tube disposed at least partially within said first tube, said second tube having a length, a lumen therethrough, an inside wall surface and an outside wall surface; and  
a bonding region bonding said second tube outside wall surface to said first tube wall surface, said second tube inside wall surface being formed of a second material for a majority of said second tube length, said first tube wall having a layer of a first material extending for a majority of said first tube length, said first material being different from said second.

28. A catheter shaft as recited in claim 27, wherein said first material and said second material form weak bonds when heat bonded to each other.

29. A catheter shaft as recited in claim 28, wherein said bonding region includes bonding between said first tube inside surface and said second tube outside surface.

30. A catheter shaft as recited in claim 27, wherein said bonding region includes bonding between said first tube inside surface and said second tube outside surface.

31. A catheter shaft as recited in claim 27, wherein said second tube wall is formed of substantially said second material therethrough.

32. A catheter shaft as recited in claim 31, wherein said first tube inside surface is formed of said second material proximate said bonding region.

33. A catheter shaft as recited in claim 32, wherein said first tube has said second material disposed over most of said first tube inside surface proximate said bonding region and distal of said bonding region.

34. A catheter shaft as recited in claim 33, wherein said first tube includes said second material as an inside layer, said first material as an outside layer, and a tie-layer disposed between said inside and outside layers.

35. A catheter shaft as recited in claim 32, wherein said first tube has said inside surface formed of said second material proximate said bonding region and has said inside surface formed of said first material distal of said bonding region.

36. A catheter shaft as recited in claim 35, further comprising a transition tie-layer disposed between said first and second materials.

37. A catheter shaft as recited in claim 36, wherein said second tube includes polyethylene and said first tube includes polyethylene proximate said bonding region and said first tube is formed of PEBA distal of said tie-layer.

38. A catheter shaft as recited in claim 27, wherein said first tube inside surface includes said first material.

39. A catheter shaft as recited in claim 38, wherein said first tube inside and outside surfaces are formed of said first material.

40. A catheter shaft as recited in claim 39, wherein said first tube is formed of said first material proximate said bonding region and distal of said bonding region.

41. A catheter shaft as recited in claim 40, wherein said second tube has a proximal portion proximate said bonding region having an outside surface formed of said first material.

42. A catheter shaft as recited in claim 40, wherein said second tube is formed of said first material in said proximal portion and formed of said second material distal of said proximal portion and has a transition tie-layer therebetween.

43. A catheter shaft as recited in claim 40, wherein said second tube is formed of said second material, said second tube proximal portion includes a tie-layer disposed over said second material and an outer layer of said first material disposed over said tie-layer.

44. A catheter shaft as recited in claim 40, wherein said second tube has said inside layer formed of said second material, a tie-layer disposed over said inside layer, and an outside layer formed of said first material disposed over said tie-layer.

45. A catheter shaft as recited in claim 40, wherein said second tube proximal portion is formed of said first material and said second tube distal of said proximal portion is bonded to said proximal portion and has an inside layer formed of said second material, a tie-layer disposed over said inside layer, and an outer layer formed of said second material disposed over said tie-layer.

46. A catheter shaft as recited in claim 40, wherein said second tube proximal and distal portions have an inside layer formed of said second material and an outside tie-layer disposed over said inside layer.

47. A catheter shaft comprising:  
a first tube including a lumen, an inside wall surface, and an outside wall surface;  
a second tube having at least a portion disposed outside of said first tube, said second tube having a length, a lumen therethrough, an inside wall surface and an outside wall surface; and

a bonding region bonding said second tube outside wall surface to said first tube outside wall surface, said second tube outside wall surface being formed of a second material for a majority of said second tube length, said first tube wall having a layer of a first material extending for a majority of said first tube length, said first material being different from said second.

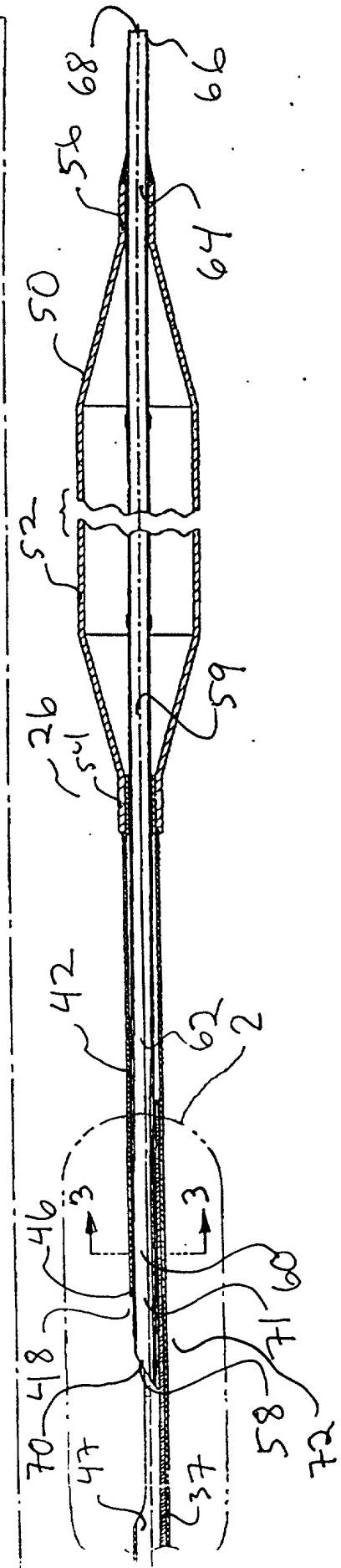
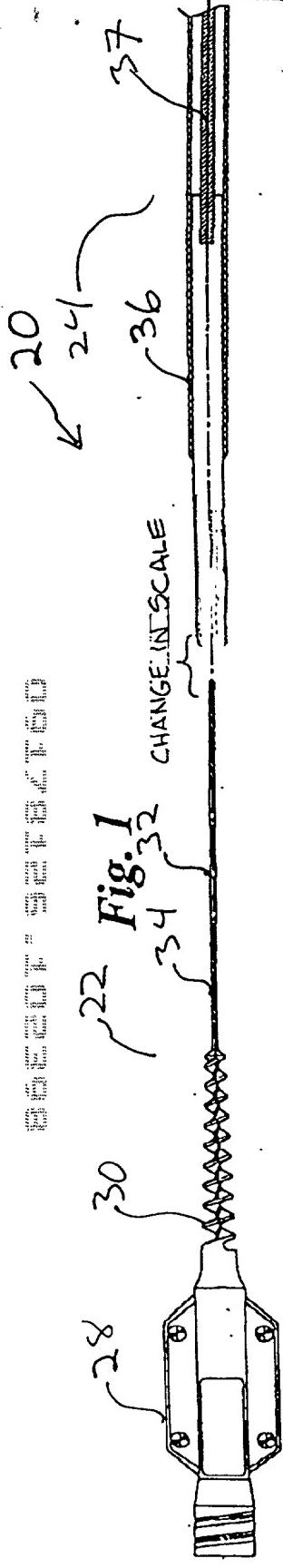
48. A catheter shaft as recited in claim 47, wherein said first material includes PEBA and said second material includes polyethylene.

Abstract of the Disclosure

A catheter having a flexible outer tube and a lubricious inner tube bonded within the flexible outer tube. One catheter has a distal outer tube formed of a substantial portion of a first, flexible material, an inner tube having a lubricious inside wall surface 5 formed of a second, lubricious material, and an outer tube wall surface compatible with heat bonding the inner tube outside wall surface to the outer tube wall surface. A preferred flexible material is polyether block amide (PEBA) and a preferred lubricious material is polyethylene. One catheter utilizing the invention includes a flexible distal outer tube having an orifice through the tube wall and an inner tube inserted through the 10 orifice having a lubricious inner layer surrounded by a tie-layer, surrounded in turn by the same flexible material forming the outer tube. One catheter has a PEBA outer tube heat bonded to a tri-layer inner guide wire tube formed of a polyethylene inner layer, a PEBA outer layer, and a PLEXAR™ tie-layer disposed between the inner and outer layers.

G E G A S T E R O

B61230P - Sheet 8 of 10



45 6 2 20 P = 22 7 22 2 C P G D

Fig. 2 808

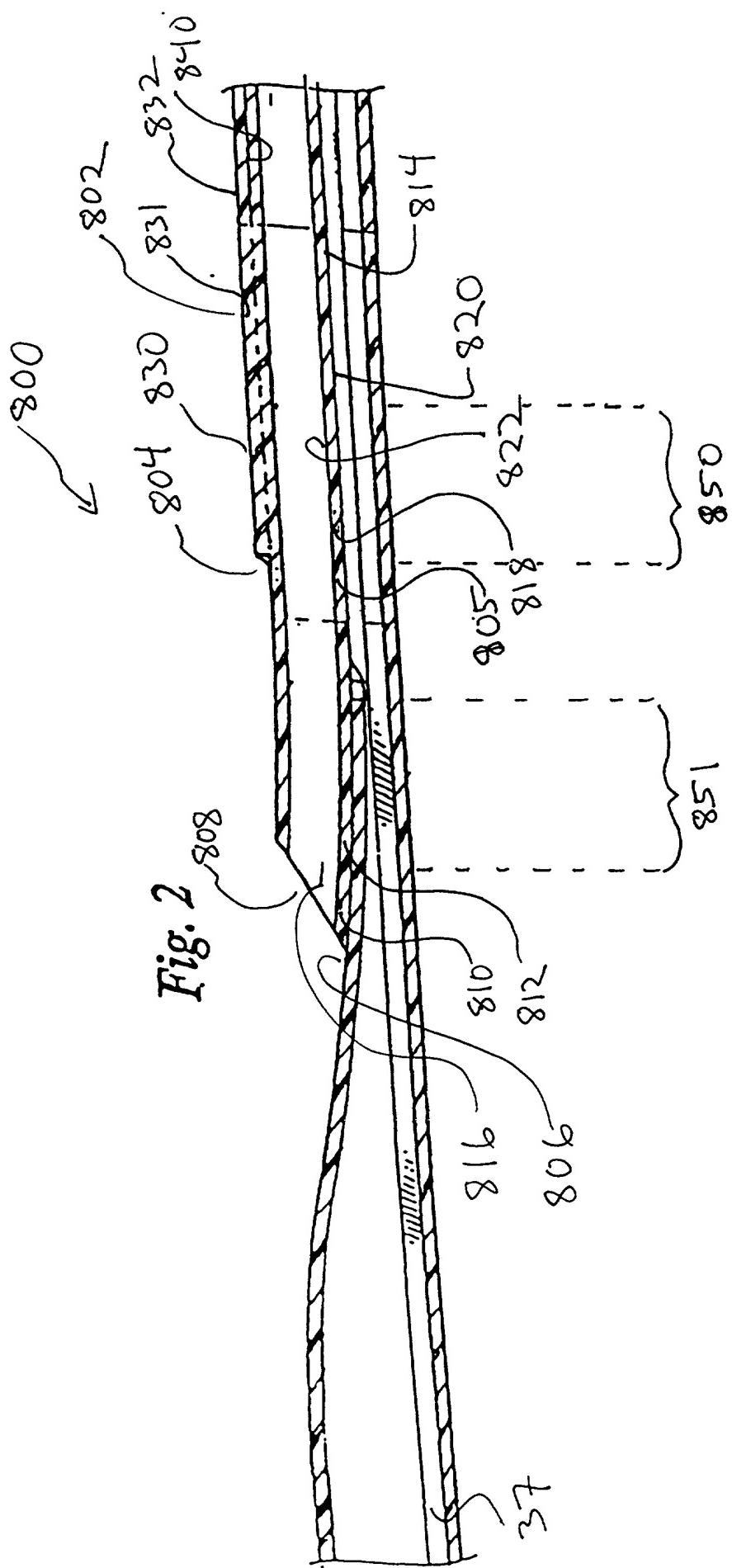
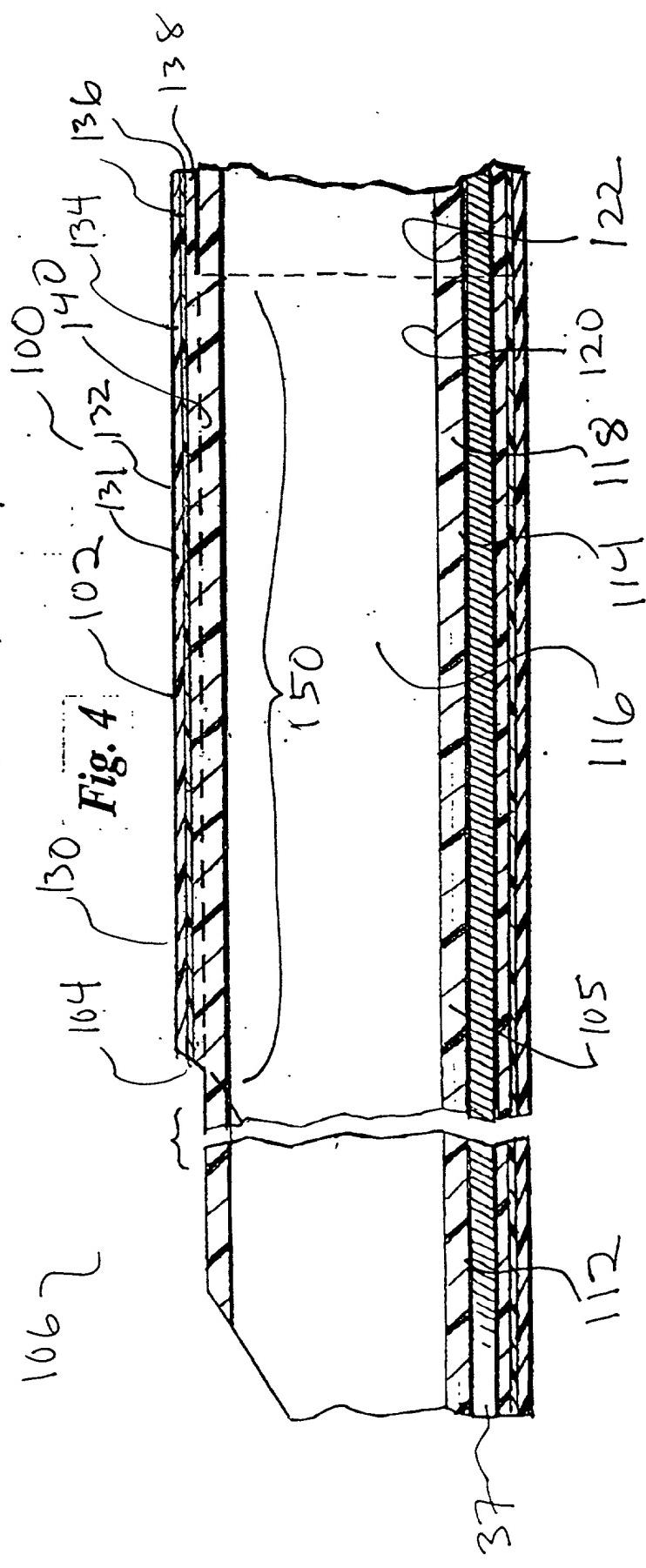
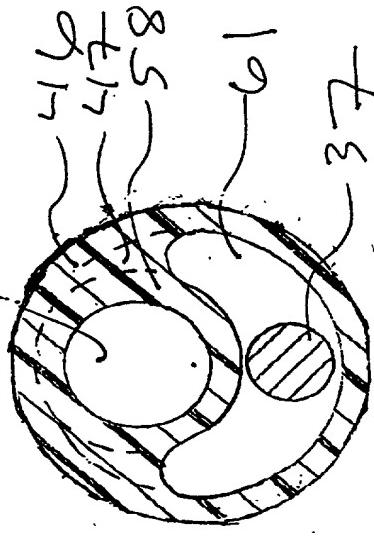


Fig. 3 59

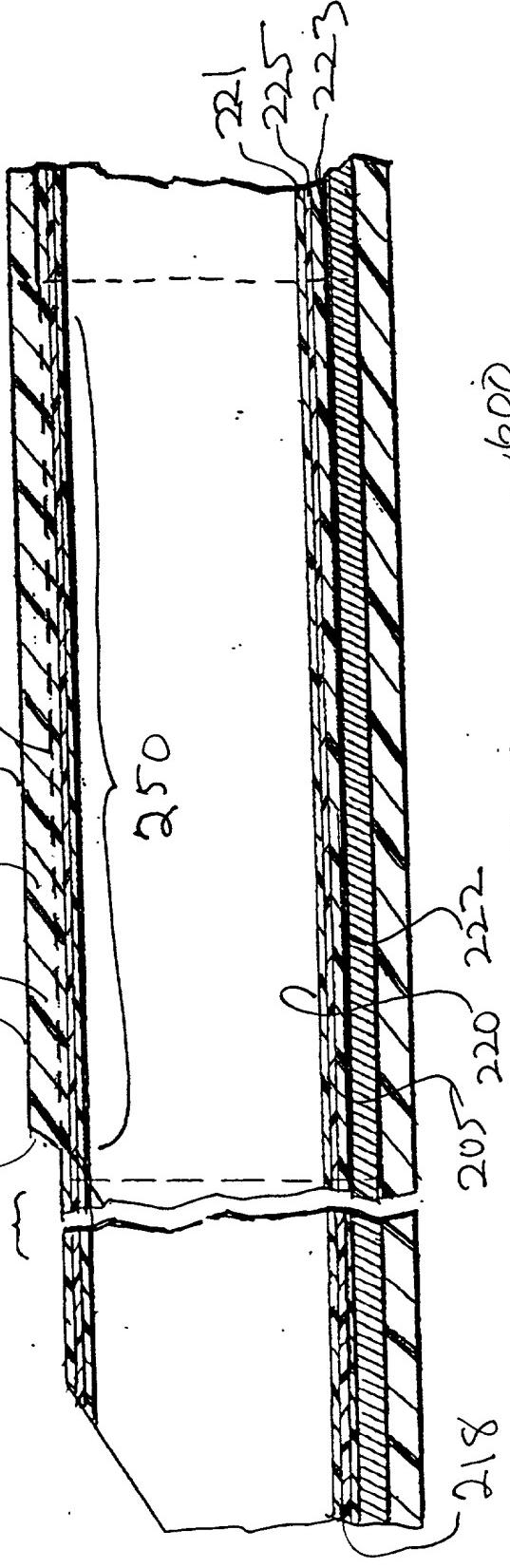


204 202 Fig. 5  
231 232 240

200

230

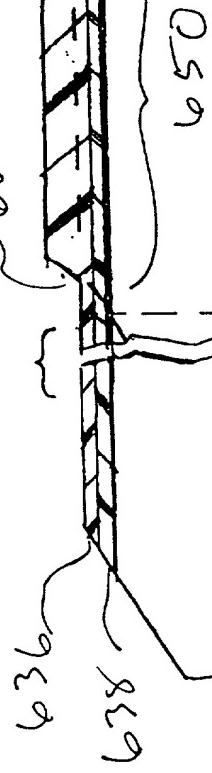
204 202 Fig. 5  
231 232 240



600

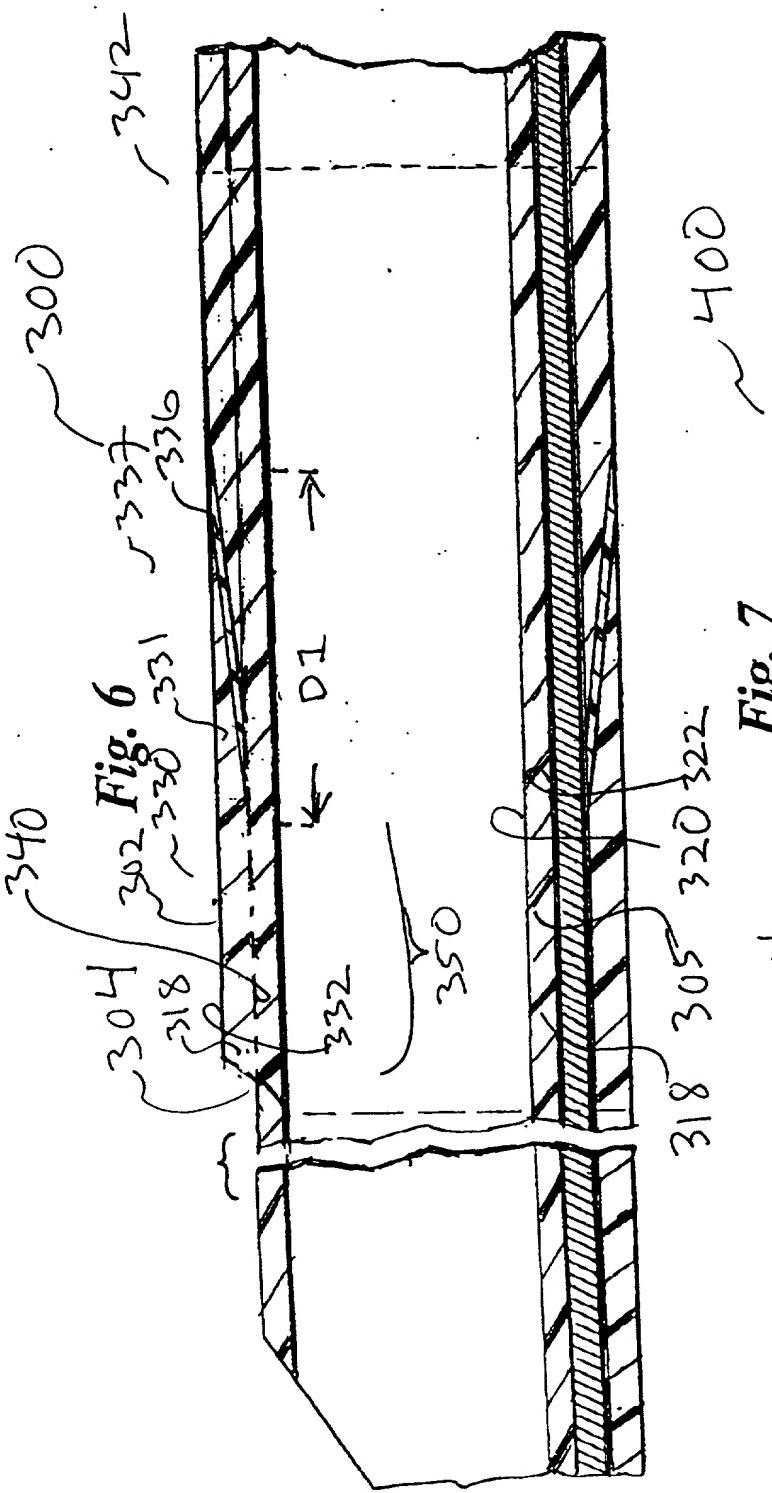
Fig. 9

604 602



636 638 641.8 605

and the other two were  
the same as the first.



304 / 302 Fig. 6

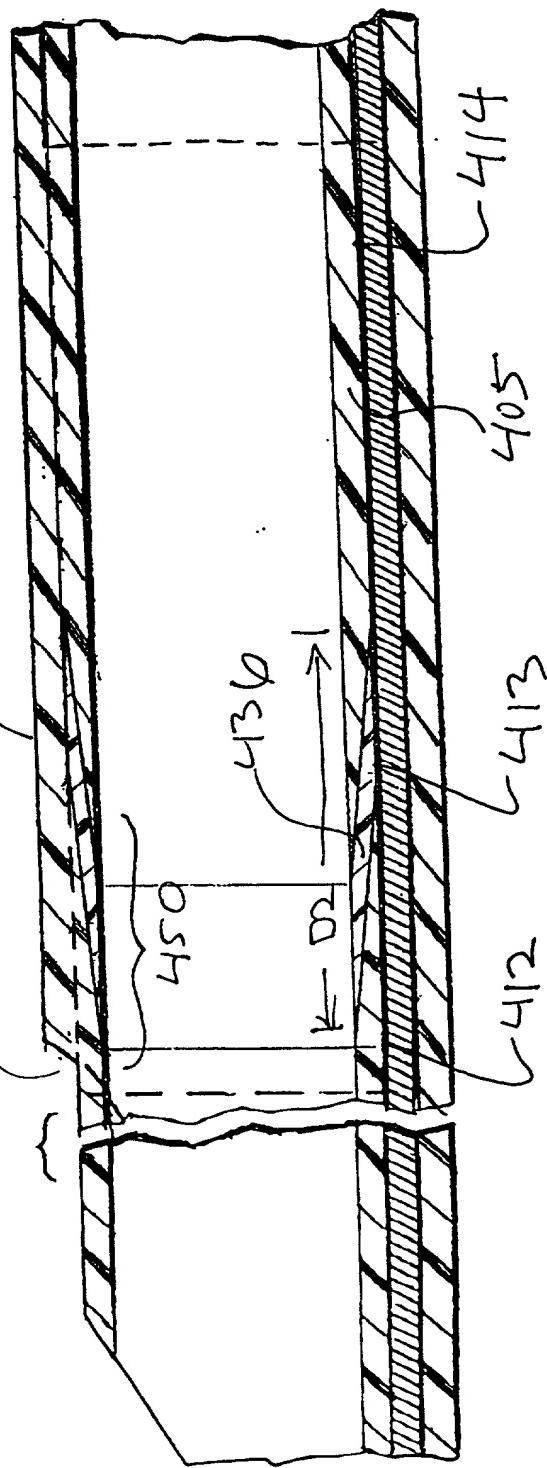


Fig. 7

800 700 600 500

Fig. 8

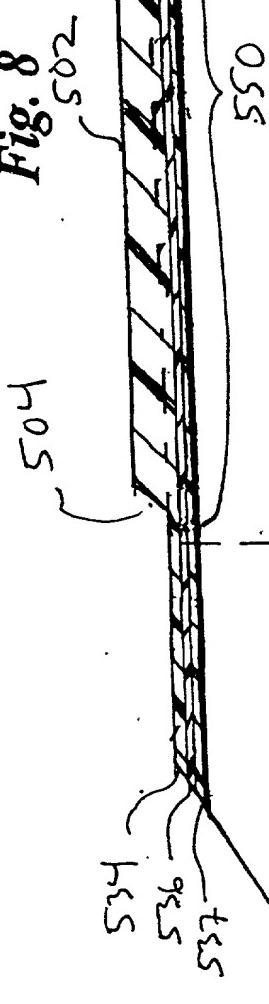
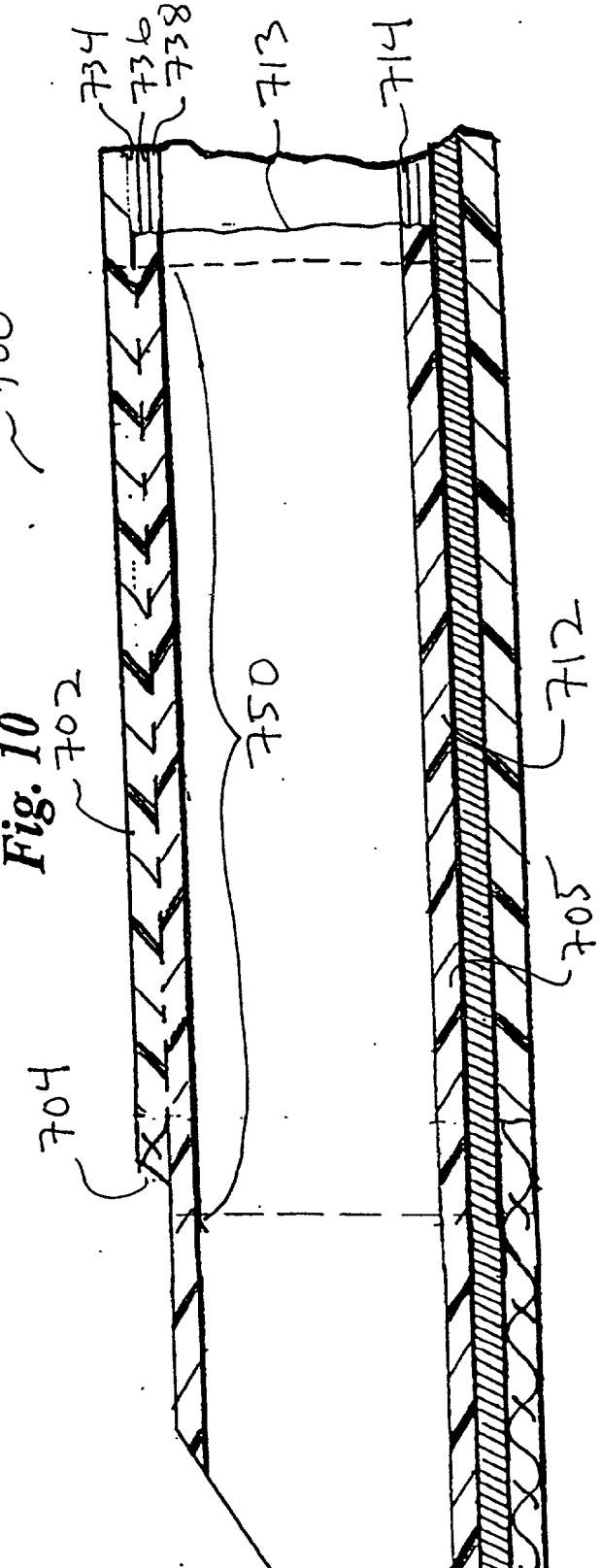


Fig. 10



## COMBINED DECLARATION/POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: CATHETER HAVING IMPROVED BONDING REGION the specification of which (check one):

X is attached hereto

\_\_\_\_\_ was filed on \_\_\_\_\_  
as U.S. Application  
Serial No. \_\_\_\_\_

\_\_\_\_\_ and was amended on (if  
applicable) \_\_\_\_\_

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefit(s) under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application(s) for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)	Priority Claimed
------------------------------	---------------------

(Number)	(Country)	(Day/Month/Year Filed)	YES	NO
_____	_____	_____	YES	NO
_____	_____	_____	YES	NO

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred

between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No. :

Filing Date :

Status (patented, pending, abandoned) :

Application Serial No. :

Filing Date :

Status (patented, pending, abandoned) :

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

David M. Crompton, Reg. No. 36,772;  
Glenn M. Seager, Reg. No. 36,926;  
Brian N. Tufte, Reg. No. 38,638;  
Craig F. Taylor, Reg. No. 40,199;  
Luke Dohmen, Reg. No. 36,783;  
Peter J. Gafner, Reg. No. 36,517;  
Robert M. Rauker, Reg. No. 40,782; and  
Todd P. Messal, Reg. No. 42,883.

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Glenn M. Seager  
CROMPTON, SEAGER & TUFTE, LLC  
331 Second Avenue South  
Suite 895  
Minneapolis, Minnesota 55401-2246  
Tel: (612) 677-9050

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon, I further declare that I understand the content of this declaration.

Full name of sole or first inventor: Timothy Stivland

Residence:

Citizenship:

Post Office Address:

Inventor's Signature \_\_\_\_\_

Date \_\_\_\_\_

Full name of second or joint inventor: Lee Khoury

Residence:

Post Office Address:

Citizenship:

Inventor's Signature \_\_\_\_\_

Date \_\_\_\_\_

**1.56 Duty to disclose information material to patentability.**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.